CONTROLS AND INDICATORS

Top Control Panel (Refer to Figure 3)

POWER ON/OFF (A) — This switch activates all systems. Start the gas flow before turning on the power; turn off the power before removing gas flow.

TEMP °C (B) — This LED is for digital temperature readout. It displays the output temperature of the proximal airway with an accuracy of ± 2°C.

LO TEMP DISABLE **(C)** — This yellow alarm indicator light illuminates during warm-up (20-30 minutes) when the power is switched to ON. During this warmup period, the low temperature alarm is automatically disabled to allow the heater to reach operating temperature.

After warmup, the LO TEMP DISABLE light will go out and the low temperature alarm system will activate. If the output temperature has already surpassed the minimum temperature of 27°C ± 1°C (during warmup), the alarm remains disabled with the yellow light on. To engage the low temperature alarm system, press the toggle switch toward ENABLE.

LO TEMP ENABLE/RESET (D) — This toggle switch allows the user to silence the low temperature alarm. If the airway temperature of 27°C ± 1°C has not been achieved within the warmup period, the low temperature alarm will activate. This may include the proximal airway probe becoming dislodged.

Important: Pressing RESET will NOT correct a low airway temperature condition. It only disables the low temperature alarm.

TEMP ALARM (E) — Any time that an alarm condition exists, this red alarm indicator light is on. Both the humidifier and the wires within the circuit are disabled when the light is on. (Refer to Alarm Indications for descriptions of alarm conditions.)

TEMP SET (F) — This knob is used to adjust the humidifier gas temperature to the patient. The digital reading on the panel displays the temperature in ${}^{\circ}$ C.

HEATER FUNCTION (G) — This green indicator light illuminates only when the heater is supplying heat to the CONCHA-COLUMN. The light's intensity varies directly with the amount of power applied to the heater. When an alarm condition occurs, the heater shuts off and the green light goes off.

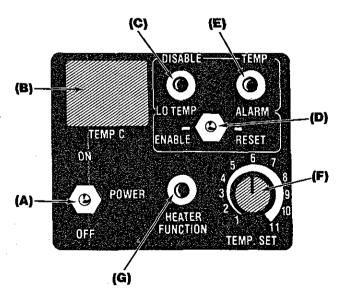


Figure 3: Top Control Panel

Heated Wire Controller

See Figure 4

HUMIDITY CONTROL (A) — This adjusts the temperature gradient between the humidifier and the patient end of the heated-wire circuit. The relative humidity delivered to the patient depends upon environmental conditions and ventilator settings.

RAINOUT ALERT (B)— This orange indicator light warns the practitioner that the desired temperature gradient between the humidifier and the patient is not being achieved.

WIRE FUNCTION (C) — This green indicator light illuminates whenever there is power available for the heated wire circuits. It will cycle on and off as the system regulates power to the wires to maintain the desired airway temperature and minimize rainout. (The light may come on even if the heated breathing circuit is not connected.)

The heated wires are **not** powered under the conditions below:

- 1. The humidifier output is less than 30°C.
- 2. The patient airway temperature is greater than 38°C.
- 3. The humidifier output is greater than 38°C and the patient airway temperature is less than 27°C.

Alarm Indications

The red audio-visual alarm on the top control panel is activated during ANY alarm condition. The power to the heater and the heated wires shuts off automatically for patient safety. Check the digital display when an alarm condition has occurred. After correcting the problem, press the RESET switch to deactivate the audible alarm and initiate the 25-minute (± 5) recycle/warmup period.

NOTE: Operator must turn the unit off to deactivate a high-temperature alarm. See TROUBLESHOOTING for display readings and warning signals.

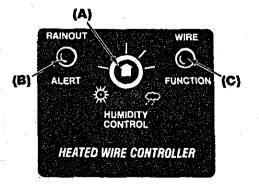


Figure 4: Heated-Wire Controller Panel

DIRECTIONS FOR USE

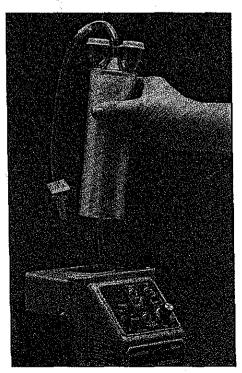
Read this entire section, including all warning and caution statements, prior to operation.

Set Up the System

The unit has three mounting plates for maximum versatility. Pole or ventilator mounting brackets are also available. Refer to PARTS AND ACCESSORIES. Mounting instructions are supplied with the bracket.

After mounting the CONCHA-THERM III Plus to the ventilator, complete the setup as follows:

- Slide the reservoir mounting bracket onto the appropriate plate at the side or rear of the unit.
- Remove the CONCHA-COLUMN from its packaging and insert the column into the top opening of the heater module with the bottom puncture pin and tubing passing through the unit. Be sure that the top and bottom tubes are clamped.

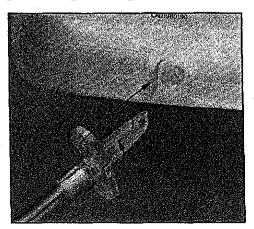


WARNING: Do not use a low-compliance column in continuous flow CPAP applications with gas flows greater than 50 LPM. There is a potential for flooding the breathing circuit and airway.

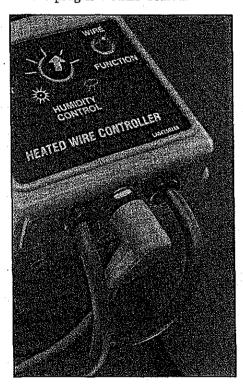
- 3. Remove the CONCHA 1500 sterile water bottle from its package. Place the bottle into the reservoir bracket.
- 4. Remove the protective caps from the ports of the CONCHA-COLUMN. Connect the tubing from the ventilator or gas source to a port on the column. Connect the inspiratory circuit tubing to the remaining port. If using a right-angle top, attach the tubing from the ventilator or gas source to the vertical port and the inspiratory tubing to the horizontal port.
- Connect the expiratory circuit tubing to the expiratory port on the ventilator.
 - WARNING: Always verify that the digital reading displays the desired temperature before connecting a breathing circuit to the patient airway.
- 6. Remove the protective sheath from the bottom puncture pin on the column tubing. CAUTION:

 Using a twisting motion, push the pin through the puncture site at the bottom of the bottle. Push the pin in all the way, as shown.

 Repeat this procedure for the top puncture pin and puncture site.

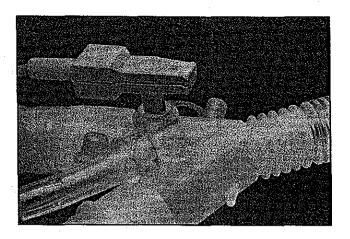


- Open all the clamps on the CONCHA-COLUMN. Standard columns have two clamps; lowcompliance columns have one clamp. Gently squeeze the bottle to initiate water flow into the column.
 - CAUTION: The heater will overheat if there is an insufficient water level to pass through the system. This may also cause erratic temperature fluctuations.
- 8. Insert the temperature probe plug into the jack at the bottom of the controller. Be certain that the plug is FULLY seated.



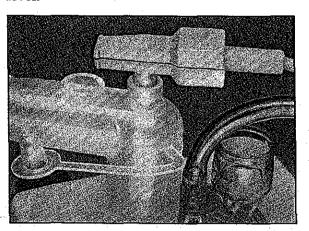
WARNING: Never operate without temperature probe(s) in their correct position. Disconnected or partially inserted probes will record inaccurate temperature readings.

Using a conventional (nonheated wire) circuit and a single probe: Insert the temperature probe into the temperature port on the inspiratory side of the patient wye.



Using a heated-wire circuit and dual probe: Insert the long-cabled probe into the inspiratory side of the patient wye and the short-cabled probe into the ported adaptor at the humidifier outlet. For heated-wire circuits, connect the power connector of the short cable to the inspiratory connector of the heated wire. Connect the power connector of the long cable to the expiratory connector of the heated wire.

CAUTION: Anhydrous air delivered to the patient does not activate an alarm. When using heated wires, ensure that the setup contains sufficient water level.

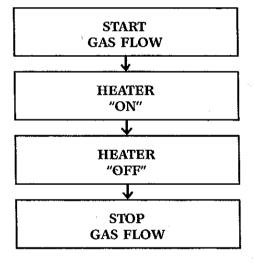


- CAUTION: Placing a temperature probe in an environment which is warmer than the temperature of the gas, such as an incubator or radiant warmer, may cause the heater to shut off and reduces the humidity and temperature to the patient.
- Refer to the ventilator manufacturer's instructions for ventilator operation and monitoring requirements.

Operation

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WARNING: Do not turn the CONCHATHERM unit "ON" until the gas flow is on and regulated. Starting the heater or leaving it "ON" without gas flow for prolonged periods may result in heat buildup causing a bolus of hot air to be delivered to the patient. Circuit tubing may melt under these conditions. Turn the heater power switch "OFF" before stopping gas flow.



- Turn on the gas flow from a flowmeter or ventilator. There must be a minimum of 5 LPM flow through the ventilator circuit.
- 2. Adjust the "TEMP. SET" knob.
 To increase the temperature
 output, GRADUALLY adjust the
 knob upward as flow
 requirements dictate. With each
 adjustment, allow adequate
 time for temperature stabilization. (This will vary

depending on flow rate, type and length of tubing, ventilating volume, breath rate, etc.)

The Low-Compliance CONCHA-COLUMN exhibits more thermal efficiency and requires less warmup time than the standard CONCHA-COLUMN. Do not make large changes in the temperature setting, particularly when using a heated circuit.

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WARNING: Setting the temperature too high may overheat the circuit, require a cool down period and cause rainout condition during the process.

- Turn the CONCHATHERM power switch to "ON" to begin a warmup period (approximately 25 minutes if using a standard column, 10 minutes if using a low-compliance column).
- 4. Observe the temperature on the digital display. RESET the alarm toggle switch if additional warmup time is required.
 NOTE: During the warmup
 - period, the yellow "Lo Temp Disable" light should be on. This prevents the system from alarming while the temperature is stabilizing. At the end of the warmup cycle, the light should go off. An alarm will activate if a minimum temperature of 27°C (± 1°) is not achieved.
- 5. Press the toggle switch to Lo
 Temp Enable if the desired
 temperature is reached before
 the warmup period is finished.
 The alarm system will activate
 automatically if the warmup
 period is complete and the
 yellow Disable light turns off.

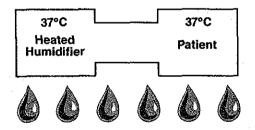
Optimize Humidity Delivery to the Patient

The Humidity Control (H/C) feature can create a temperature difference up to 3°C between the patient and heater. Adjusting the temperature gradient between the humidifier and the patient end of the heated circuit allows the practitioner to compensate for ventilatory conditions and environmental variables. This allows control of the relative humidity delivered to the patient.

The following examples will assist with selecting the appropriate setting for the patient. In this example, the desired patient temperature is 37°C. The raindrops illustrate the amount of condensation in the circuit.*

EXAMPLE A



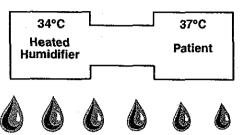


With the H/C knob pointing straight up, the temperature gradient is zero. This allows the temperature to be constant throughout the length of the ventilator circuit.

symbol for condensate

EXAMPLE B

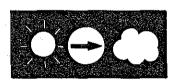


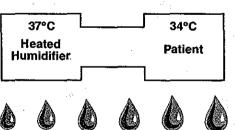


With the H/C knob at the full sunshine position, additional heat is supplied in the circuit. The heater temperature is 3°C cooler than the proximal airway temperature. This delivers less humidity to the patient and potentially less rainout within the ventilator circuit.

■ IMPORTANT: A humidity deficit may be delivered to the patient, depending on the temperatures and ventilatory parameters used.

EXAMPLE C





With the H/C knob at the full rain cloud position, the heater temperature is 3°C warmer than the proximal airway temperature. More humidity can be delivered to the patient. There is a potential for increased rainout within the ventilator circuit, as illustrated by the raindrops.

Routine Checks and Operating Maintenance

- Observe the condensation levels in the tubing with every ventilator circuit check. Drain as necessary. When using the CONCHATHERM III Plus appropriately, the inspired gas can be up to 100% humidity with minimal rainout.
 - NOTE: Since less heat is required when using a heated-wire circuit, a lower temperature setting may be used. Decrease the setting before starting the heater. Allow time for stabilization after each adjustment.
- Replace the column with each ventilator circuit change or at least every 48 hours.
 - a. Avoid skin contact with HOT metal surfaces.
 - NEVER reprocess the column. Columns are designed for single patient use.

WARNING: The metal surfaces of the column or heater may be HOT.

 Check the reservoir bottle for adequate sterile water supply. A water supply at or below the replacement line on the bottle may cause erratic temperature fluctuations. The reservoir can be replaced at any time without interrupting the gas flow.

To change the reservoir bottle:

a. Close all clamps before removing the reservoir bottle.

- b. Carefully remove the bottle from its holder and lower the bottle to a level below the column. Orient the bottle so that the holes are on top. Remove the lower puncture pin from the bottle.
- c. Discard the used reservoir bottle and place a new CONCHA 1500 sterile water reservoir bottle in the reservoir bracket.
- d. Press the lower pin through the puncture site at the bottom of the bottle. TWIST and PUSH the pin in all the way. Repeat this procedure for the top puncture pin and puncture site.
- e. Open all clamps on the CONCHA-COLUMN and squeeze the bottle to initiate flow into the column. (These instructions are also provided with each column.)
- 4. Check the digital temperature display on the CONCHATHERM III Plus heater whenever an alarm condition occurs and when making any adjustments to the setup.

TROUBLESHOOTING AND MAINTENANCE

ANY alarm condition activates the red audio-visual alarm on the top control panel. The power to the heater and the green light go off automatically for patient safety. Check the digital display to determine which alarm condition has occurred.

When using a conventional circuit (no heated wires) and a single probe, the Heated Wire Controller does not function and the heater operates as a CONCHATHERM III. The Wire Function light will not illuminate. No wires within the circuit heat the inspired gas and rainout may occur. The RAINOUT ALERT light will illuminate.

After correcting the problem, press RESET to deactivate the audible low temperature alarm for an additional 25-minute warmup cycle.

If the temperature exceeds the low limit, press ENABLE to reactivate the low temperature alarm. This will bypass the remaining warmup time.

		•			
Digital Display	Signal	Suspected Condition	Corrective Action		
00 to 03°C	Unit alarms immediately, reset does not clear alarm. Heater shuts off.	 Temperature cable jack not properly connected or discon- nected at unit 	Secure cable con- nection at unit.		
		2. Wire in cable broken	2. Replace probe cable		
		3. Heater sensor fails	3. Remove CONCHA- THERM III Plus from use for repair		
70 to 90°C	Unit alarms. Heater shuts off.	No electrical current going to the probe	1. Secure probe connections		
			2. Replace probes		
Low Temp Alarm ≤ 28°C	Audible and visual low temperature alarm. Heater shuts off.	1. Temperature output <26-28°C in warm- up period	Reset to initiate warm- up cycle		
•		2. Temperature drops < 26-28°C	2. Reset to iniate warm- up cycle		
		Proximal airway probe become dislodged	3. Secure probe connection		
High Temp	Unit alarms	1. Temperature output 39-49°C	(a.) Allow temperature to decrease (b.) Reset low temperature switch		
		2. Probe may have shorted	2. Replace probe		
		3. Probe becomes dislodged	3. Secure probe connection		

Preventative Maintenance

Periodically perform a diagnostic test as described below. Refer to TROUBLESHOOTING for an explanation of display readings.

Diagnostic Test

The procedures for usage with a heated-wire circuit or nonheated-wire circuit are similar. The only differences are the air flow, temperature setting, and humidity control setting.

- Set up the unit with a full reservoir bottle ready for normal operation. Insert a new, standard column into the heater. Connect the column tubing to the reservoir bottle.
- Provide continuous 68 to 78°F dry air to one of the ports at the top of the column. Use the settings described below.

	LPM	Temp. Setting	Humidity Control
Using a heated circuit:	12	5	Fully clockwise
Using a nonheated circuit:	10	7	Not applicable

3. Install the inspiratory limb of a 72" circuit onto the right-angle port (or either port when using parallel ports) of the column. Connect the temperature probe to the ported wye at the patient end. If using a heated-wire circuit and dual temperature probes, connect the long-cabled probe to the ported wye at the patient end and the short-cabled probe to the ported adaptor at the humidifier.

- 4. Attach a digital thermometer with an accuracy of ± 1°C (or better) between the end of the tubing and a ported adaptor attached to the wye.
- Apply power to the heater. Allow 35 to 45 minutes for the temperature to stabilize.

TEST RESULTS SHOULD BE:

When room temperature is 68 - 76°F and the digital display is 33 - 37°C, the thermometer reading should be 90.5 - 98.6°F (33 - 37°C).

7. If the patient airway temperature is not between 33 and 37°C, return the unit for calibration. (See SERVICE in this manual.)

Cleaning

HEATER: Use a 3% hydrogen peroxide solution or sodium hypochlorite to disinfect the outer surfaces. DO NOT use alcohol or solvent on the unit. A CAUTION: Never autoclave, gas sterilize (EtO), irradiate, pasteurize or submerge in solution.

PROBES: Wipe tips and cable with alcohol, chlorine bleach, Sporiciden® or hydrogen peroxide only.

Service

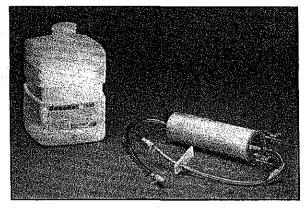
User performed repairs during the warranty period will void the CONCHATHERM III Plus warranty. If your CONCHATHERM III Plus requires service, contact the Customer Service Department at 1-800-848-3766 (toll free) or 1-714-676-5611, for a Return Goods Authorization (RGA) number.

You may authorize replacing your heater with a remanufactured heater. This authorization permits Hudson RCI to ship you a replacement heater within 7 days after receiving your old heater. If you choose to have your serial-numbered heater serviced and returned, repairs and turnaround time may be longer than with the replacement program.

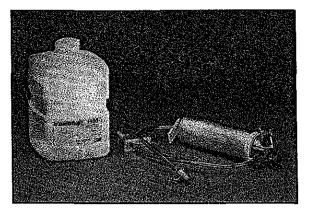
When returning a heater for service, please provide the following information in writing:

- Your RGA number obtained from Hudson RCI Customer Service.
- Written approval to replace your heater with a like-new warranted heater OR written approval to service and return your original, serial-numbered heater.
- Description of the nature of the malfunction. Please give specific details and describe the application.

PARTS AND ACCESSORIES



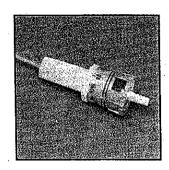
Cat. No. 385-30 and 385-70 (vertical ports)
Low-Compliance and Standard Columns available
Cat. No. 381-50
(Sterile water sold separately, 6 each)



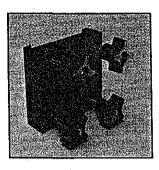
Cat. No. 385-20 and 385-60 (right-angle port)
Low-Compliance and Standard Columns available



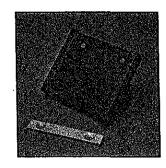
Cat. No. 384-26



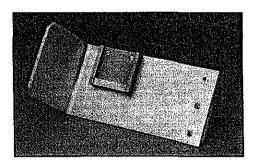
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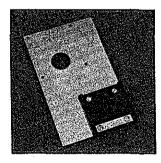
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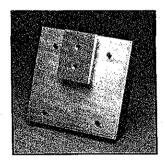
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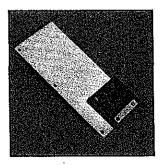
Cat. No. 386-65



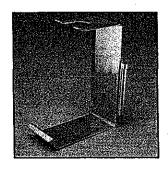
Cat. No. 386-72



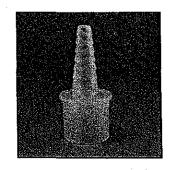
Cat. No. 386-75



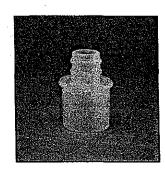
Cat. No. 386-77



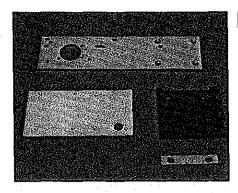
Cat. No. 386-81

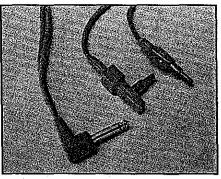


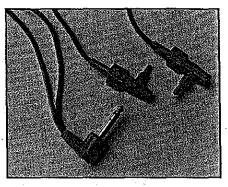
Cat. No. 384-00



Cat. No. 384-10



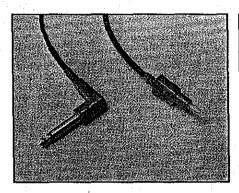


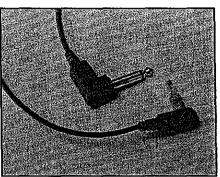


Cat. No. 386-70

Cat. No. 380-91

Cat. No. 380-89





Cat. No. 380-93

Cat. No. 380-92

Cat. No. 380-93	Car. No. 3	QU-92		100	_
				23	Cat. No.
CONCHATHERM HI Plus Humidifier Heater, 21 volt					380-88
CONCHATHERM III Plus Humidifier Heater, 16 volt					380-90
CONCHAPAK® Sterile Water 1650 ml., Low-Complian	ice Pediatric/	Adult CO	NCHA-COLU	MN (6 ea.)	385-20
CONCHAPAK Sterile Water 1650 ml., Low-Compliand vertical ports (6 ea.)	ce Pediatric/A	dult CO	NCHA-COLUM	N with	385-30
CONCHAPAK Sterile Water 1650 ml., with CONCHA	-COLUMN (5 ea.)	-	4,7	385-60
CONCHAPAK Sterile Water 1650 ml., with CONCHA	-COLUMN v	vith <i>verti</i>	ical ports (6 ea)	385-70
CONCHA1500, Sterile Water 1650 ml. Reservoir (6 ea	a.)				381-50
Adult Dual Thermistor Probe for use on CONCHATHI	ERM III Plus,	380-88			380-89
Pediatric Dual Thermistor Probe for use on CONCHA	THERM III F	lus, 380-	90	100	380-91
Adult Thermistor Probe for use on CONCHATHERM	III		5		380-92
Pediatric Thermistor Probe for use on CONCHATHER	M III		•	· · · · · · · · · · · · · · · · · · ·	380-93
CONCHA Tubing Adaptor narrow bore (30 ea.)					384-00
CONCHA Hose Adaptor 5/16 inch (30 ea.)	•		•		384-10
CONCHA Oxygen Diluter - Adjustable 26% to 90%	30 ea.}				384-26
CONCHA Nebulizer Adaptor - Adjustable 28% to 909		٠.	And the second second		388-28
CONCHATHERM Reservoir Bracket for Cat. Nos. 380)-00, 380-10				386-00
CONCHATHERM Universal Pole Bracket					386-10
CONCHATHERM Wall Bracket					386-40
CONCHATHERM Bird ¹ 6400 ST and 8400 ST Bracket	t i		and the second		386-65
CONCHATHERM Universal Ventilator Bracket MA-1	2				386-70
CONCHATHERM PB-7200 ² Ventilator Bracket				*	386-72
CONCHATHERM Siemens ³ Ventilator Bracket					386-75
CONCHATHERM Bear I & II Ventilator Bracket					386-77
CONCHATHERM III 1650 ml. Reservoir Bracket for	Cat. Nos. 38	0-80, 380	-88, 380-90		386-81

Registered trademark of Bird Products Corporation
 Registered trademarks of Puritan-Bennett Corporation
 Registered trademark of Siemens-Elema
 Registered trademark of Bear Medical Systems, Inc.

WARRANTY

The 380-88 and 380-90 CONCHATHERM III Plus heaters are warranted by Hudson Respiratory Care Inc. against defects in materials and workmanship for a period of one year from the date of original purchase to end user. During the warranty period, we will repair or, at our option, replace at no charge any heater that proves to be defective, provided you return the heater, shipping prepaid, to Hudson Respiratory Care Inc. This warranty does not apply if the device has been damaged by accident, misuse, or as a result of service or modification by someone other than Hudson Respiratory Care Inc.

No other express warranty is given. The repair or replacement of the device is your exclusive remedy. ANY OTHER IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS IS LIMITED TO THE ONEYEAR DURATION OF THE WRITTEN WARRANTY. Some states, provinces or countries do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. IN NO EVENT SHALL HUDSON RESPIRATORY CARE INC. BE LIABLE FOR CONSEQUENTIAL DAMAGES. Some states, provinces or countries do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

This warranty gives you specific legal rights, and you may have other rights which vary from state to state, province to province or country to country.

This device is sold on the basis of specifications applicable at the time of manufacture. Hudson Respiratory Care Inc. shall have no obligation to modify or update this device once sold.

For more information about the CONCHATHERM III Plus warranty, contact an authorized Hudson Respiratory Care Inc. distributor or Hudson Respiratory Care Inc. Also, refer to *Service* in this manual.



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